DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/23/2010 has been entered.

Rejections and objections that are not reiterated in the current office action are hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, are 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US Publication 20010014322 (Chen) in view of Ernest Brody “Biological activities of bovine glycomacropeptide”, British Journal of Nutrition (2000), 84, Suppl. 1, S39-S46 (hereinafter Ernest) and further in view of Farmer et al. US 7374753 (Farmer).

Chen teaches a beneficial microbe composition, protective materials for the microbes, method to prepare the compositions and uses thereof. The invention provides a microbe composition which: (1) exerts a control mechanism for the micro ecological balance between enteric microbes and their human host; (2) is antagonistic to pathogens and/or potential pathogens such as salmonella, shigella, E. coli and vibrio cholerae, especially when the pathogens and/or potential pathogens are resistant to various antibiotics; (3) is effective in treating various kinds and degrees of diarrhea; (4) and is effective in decreasing the levels of endotoxin [0022]. The composition contains proteins such as 3.5-4% skimmed milk protein and

3% yeast extract [0061 and claim 15]. Note that the milk protein includes whey. It is also noted that reciting "the effects of infection includes failure of gut epithelial integrity diarrhea and other COX-2 mediated effects" in claim 2 is an inherent effect of such infections and is inherently included in such patients. The composition is used orally as required in instant claim 11 [see all patent publication e.g. paragraphs 0179 and 180].

Chen is silent towards the peptones and the number of amino acids included in the peptones.

Ernest teaches bovine k-Caseino glycomacropeptide (GMP) ability of to bind cholera and Escherichia coli enterotoxins, inhibit bacterial and viral adhesion, suppress gastric secretions, promote bifido-bacterial growth and modulate immune system responses. The reference teaches that the oral composition comprises peptide chain and that the protein used is whey protein (see arrows in page S40). Ernest teaches that when the GMP was treated with sialidase, which hydrolyses the sialic acids, complete loss of cholera toxin inhibiting activity occurred. The peptide chain must also participate in the binding as partial loss of cholera toxin inhibiting activity occurred after treatment with proteases. The activity was narrowed to a peptide fraction obtained by ion-exchange chromatography (page S41, see arrow). The inhibitory activity was due to K-casein, which upon rennet hydrolysis, results in inhibitory activity being found in the GMP fraction (see arrow, page S43). The stronger of these was a 700-2000 Dalton peptide fraction. It is noted that although the reference does not recite the number of amino acids as required in instant claim 5, it is inherent that Ernest teaches the same number of amino acids because the reference uses the same protein source (whey) and the same process of hydrolysis. Note also that instant specification recognizes the peptones used in the current invention as having molecular weights of the peptones less than 3kDa (see spec. page 3), thus, it is clear that inherently Ernest discloses the same amino acids number.

Therefore, it would have been obvious to a person having ordinary skill in the art to include whey peptone having reduced number of amino acids as disclosed by Ernest in the composition decreasing endotoxin effect taught by Chen to enhance the effect of controlling the endotoxin effects and also because both disclosures are in the same field of endeavor.

Neither of the references teaches using the composition for treating endotoxin as an adjuvant.

Farmer teaches a composition for oral administration to the intestinal tract for inhibiting bacterial gastrointestinal infections. The compositions of the invention suitable for use in preventing, treating or controlling gastrointestinal bacterial infections, particularly infant bacterial infections, by organisms capable of producing enterotoxins and infection. The composition can be in the form of a pharmaceutically acceptable carrier suitable for oral administration to a human infant, preferably, a powdered food supplement, a infant formula or an oral electrolyte maintenance formulation (col. 4, lines 27+).

It would have been obvious to a person having ordinary skill in the art at the time the current invention was made to use the composition made by Chen and modified by Ernest as a pharmaceutical carrier as disclosed by Farmer because Farmer teaches that compositions for treating enterotoxic infections can be used as pharmaceutically acceptable carrier suitable for oral administration to a human infant, preferably, a powdered food supplement, a infant formula or an oral electrolyte maintenance formulation (col. 4, lines 27+).

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5, are 8-11 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on Monday-Friday 10:00 AM -2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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